MAY 2 4 2013

SECTION 2 - 510(k) SUMMARY

HEALIX ADVANCE™ KNOTLESS BR ANCHOR

Submitter:	DePuy Mitek *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767
Contact Person	Yayoi Fujimaki Regulatory Affairs Senior Associate DePuy Mitek *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767, USA Telephone: 508-828-3541 Facsimile: 508-977-6911 e-mail: yfujima1@its.jnj.com
Name of Medical Device	Proprietary Name: HEALIX ADVANCE KNOTLESS BR ANCHOR Classification Name: Fastener, Fixation, Biodegradable, Soft tissue Common Name: Bone Anchor
Substantial Equivalence	The HEALIX ADVANCE KNOTLESS BR ANCHOR is substantially equivalent to: ▪ K112249 Mitek Healix Knotless BR Anchor
Device Classification	Single/multiple component metallic bone fixation appliances and accessories, classified as Class II, product code MAI regulated under 21 CFR 888.3030.
Device Description	The proposed HEALIX ADVANCE KNOTLESS BR ANCHOR is a cannulated, threaded knotless anchor designed to secure soft tissue to bone. The proposed anchor is manufactured from the absorbable material "Biocryl® Rapide™" (15/85% β – TCP/PLA PGA copolymer) loaded on a disposable inserter driver with #2 ORTHOCORD® suture (K040004, K043928). The anchors are offered in two sizes (4.75 mm and 5.5 mm).
Indications for Use	The HEALIX ADVANCE KNOTLESS BR Anchors are indicated for use in the following procedures for reattachment of soft tissue to bone: Shoulder • Rotator Cuff • Biceps Tenodesis

Comparison of Technological Characteristics	Substantial equivalence to the predicate device has been justified by similarity analysis of indications, design, material, operation principle and device performance data. Performance testing ensured that the feature does not raise any new issues of safety and efficacy.
Safety and Performance	**Non-clinical Testing** Performance requirement of the proposed device is to secure soft tissue to bone during soft tissue healing period. Fixation force testing was performed under *in vitro* condition throughout two times of healing period. The data shows that the proposed device performs similarly to the predicate devices. Material biocompatibility has been also confirmed. Thus, the proposed device does not raise any new issue of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 24, 2013

DePuy Mitek, A Johnson & Johnson Company
% Yayoi Fujimaki
Regulatory Affairs Senior Associate
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K130917
Trade/Device Name: HEALIX ADVANCE™ Knotless BR Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI
Dated: May 16, 2013
Received: May 17, 2013

Dear Yayoi Fujimaki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DePuy Synthes
MITEK SPORTS MEDICINE

Indications for Use

510(k) Number (if known): K130917

Device Name: HEALIX ADVANCE™ KNOTLESS BR Anchor

Indications for Use:

The HEALIX ADVANCE KNOTLESS BR Anchors are indicated for use in the following procedures for reattachment of soft tissue to bone:
Shoulder

- Rotator Cuff
- Biceps Tenodesis

Prescription Use ___x___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices